

PTO/SB/088 (04-03)

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete If Known

Application Number	10/795,819
Filing Date	March 8, 2004
First Named Inventor	BAKHUTASHVILI, Vladimir
Art Unit	1851
Examiner Name	Ruth A. Davis
Attorney Docket Number	627-B-US

Sheet 1 of 1

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
RAD	1	Supplemental European Search Report for LAJOR BIO TECH, INC., European Application No. 01959894.5, Filed March 7, 2003, Dated March 14, 2005. [Exhibit 1]	
RAD	2	RUNIC, et al., "Apoptosis and Fas Expression In Human Fetal Membranes"; Journal of Clinical Endocrinology and Metabolism, Vol. 83, no. 2, February 1998 (1998-02) pages 680-666, XP002319582. [Exhibit 2]	
RAD	3	IWAMA, et al., "Serum Concentrations of Fas Antigen and Soluble Fas Ligand In Mother and Newborn"; Archives of Gynecology and Obstetrics, Vol. 263, no. 3, February 2000 (2000-02), pages 108-110, XP002319583. [Exhibit 3]	

Examiner Signature	<i>[Signature]</i>	Date Considered	6/2/05
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First Named Inventor	BAKHUTASHVILI, Vladimir
Art Unit	Not Yet Known
Examiner Name	Not Yet Known
Attorney Docket Number	627-B-US

Sheet	1	of	2
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U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

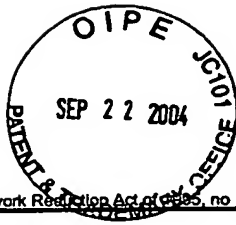
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Signature**

Date Considered

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/795,819
Filing Date	March 8, 2004
First Named Inventor	BAKHUTASHVILI, Vladimir
Art Unit	NOT YET KNOWN
Examiner Name	NOT YET KNOWN
Attorney Docket Number	627-B-US

Sheet 2 of 2**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
LAD	1	PCT Written Opinion for Lajor Biotech, Inc, Int'l Application No. PCT/US01/41666 Filed on August 9, 2001, Dated August 4, 2004.	
LAD	3	Response to August 4, 2004 Patent Cooperation Treaty (PCT) Written Opinion, Dated September 3, 2004	

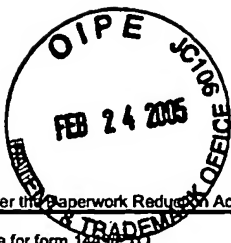
Examiner Signature	<u>LAD</u>	Date Considered	<u>6/2/05</u>
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Substitute for form 1449-110

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known

Application Number	10/795,819
Filing Date	March 8, 2004
First Named Inventor	Vladimir BAKHUTASHVILI
Art Unit	NOT YET KNOWN
Examiner Name	NOT YET KNOWN
Attorney Docket Number	627-B-US

Sheet 1 of 1

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
KAM	1	1. PCT Notification of Transmittal of International Preliminary Examination Report and International Preliminary Examination Report for Lajor Bio Tech, Inc., International Application No. PCT/US01/41666 Filed on August 9, 2001 Dated January 21, 2005	
HAD	2	Wilson et al., The Effect of Interleukin-16 and Its Precursor on T Lymphocyte Activation and Growth. Growth Factors. June 2004, Vol. 22, No. 2, pages 97-104.	

Examiner Signature		Date Considered	6/2/05
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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Application Number	Not Yet Known
		Filing Date	Herewith
		First Named Inventor	BAKHUTASHVILI
		Art Unit	1651
		Examiner Name	Ruth Davis
Sheet 1 of 1	Attorney Docket Number	627-B-US	

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
LAV	1	US-09/928,178	08-22-2002	Vladimir BAKHUTASHVILI	
		US-			
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FOREIGN PATENT DOCUMENTS*						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

Examiner Signature		Date Considered	6/2/05
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Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

627-A

Serial No.

09/928,178

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

BAKHUTASHVILI, Vladimir

Filing Date

August 9, 2001

Group

1614

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

LAM	1	Bakhutashvili, A. et al.
		Immunopharmacology of preparation. Plaferon-LB. Intern J Immunorehab 1994; 1 (S): 44. (Abstract) (Exhibit 1)
	2	Bakhutashvili, A. et al.
		Plaferon LB - a new immunodilatory drug. Abstracts XVI European Congress of Allergology and Clinical Immunology, Madrid, Spain, 25-30 June 1995. Europ J Allergy Clin Immunol 1995; 50(26): 9. Abstract # OC-009. (Abstract) (Exhibit 2)
	3	Bakhutashvili, A. et al.
		Amnion apoptosis modulator. Int J Immunorehab 2001, 3(2): 17-22. (Exhibit 3)
V	4	Bakhutashvili, V. et al.
		Immunomodulatory activity of Plaferon-LB. Georg Symp Project Development and Conversion; Collection of Reports 1995; 189-191. (Exhibit 4)

NO Transition :-	5	Bakhtashvili, V. et al. The perspectives of a new immunomodulator Plaferon LB in endocrinologic practice. Proceedings of Tbilisi State Medical University 1996; 32: 21-23. (Exhibit 5)
Not considered ↓	6	Bakhtashvili, V. et al. Effect of Plaferon-LB during treatment of medicamentously resistant form of epilepsy. Int. J Immunorehab 1996; 3: 28-37. (Exhibit 6)
LAP	7	Bakhtashvili, V. et al. Cardioprotective effects of Plaferon LB in a canine model. The J Heart Failure 1997 May; 4(1): 38. Abstract #151. (Abstract) (Exhibit 7)
	8	Bakhtashvili, V. et al. Human placenta antioxidant compounds of peptide nature. 11th International Symposium on Atherosclerosis, Paris 1997 October 5-9, Int J Res Invest on Atherosclerosis and Related Diseases October 1997; 134(1-2): 199. Poster # 3.P.4. (Abstract) (Exhibit 8)
	9	Bakhtashvili, V. et al. Some pharmacological characteristics of Immunomodulator Plaferon-LB. 10th International Congress of Immunology in New Delhi, 1998 Nov 1-6; The Immunologist 1998 Suppl 1: 586. (Abstract) (Exhibit 9)
	10	Bakhtashvili, V. et al. "Plaferon," Drugs of the Future 1999; 24(9): 974-977. (Exhibit 10)
	11	Bakhtashvili, V. et al. Use of Plaferon-LB and cromoglycate in patients with symptomatic asthma. Int J Immunorehab 1999; 11: 214-215. (Exhibit 11) *Translated abstract only
	12	Bakhtashvili, V. et al. Bronchotropic Effect of Plaferon-LB. Int J Immunorehabilitation 1999; 5: 51-53. (Exhibit 12)
	13	Bakhtashvili, V. et al. Dinamics of some immunological indices in case of Plaferon-LB therapy. Europ. J. Allergy and Clin Immun 1999; 54(52 S): 77. Abstract # P37. (Abstract) (Exhibit 13)
	14	Bakhtashvili, V. et al. Results of treatment of acute B hepatitis by Plaferon LB. Bulletin of Georgian Academy of Science, Biology Series 1999 25 (1-3):21-23. (Exhibit 14)
↓	15	Bakhtashvili, V. et al. Impact of perioperational immunotherapy upon nonspecific resistance and specific immune status in patients with bowel cancer and upon frequency and spectrum of complications in nearest postoperative period. Int J Immunorehab 2000;2 (2): 4. Abstract # 3. (Abstract) (Exhibit 15)

16	Beridze M. et al.
	Effect of Plaferon-LB on several clinical and neuroimmunological indices. Georgian Medical News 1998; 6(39): 27-30. (Exhibit 16) * Summary only
17	Beridze M. et al.
	Neuroprotective action of immunomodulator Plaferon-LB. Int J of Immunorehab 1999; 14: 114. Abstract # 15. (Abstract) (Exhibit 17) * translated Summary only
18	Hvadagiani G. et al.
	Protective effect of Plaferon LB preparation on acute ischemic renal injury in experiments. Archivum Urologium Belgrade 1989; 30: 45-51. (Exhibit 18)
19	Chavchanidze D et al.
	Changes of blood paramagnetic centers under the influence of shock waves on kidneys and membrane-protector effect of Plaferon-LB in experiment. Bulletin of the Georgian Academy of Sciences 1998; 158(2): 332-335. (Exhibit 19)
20	Chavchanidze D et al.
	Determination of traumatic influence of shock waves and membrane-protecting effects of Plaferon-LB on the renal parenchyma during extracorporeal lithotripsy in experiment. Proc Georgian Acad Sci; Biol Ser 1998; 24(1-6): 53-59. (Exhibit 20)
21	Cheishvili N et al.
	Effect of Plaferon-LB on proliferative activity of human peripheral blood mononuclear cells and murine splenocytes. Reports of Georgian Academy of Science 1994; 150 (1): 142-143. (Exhibit 21) * translated Summary only
22	Chikovani T et al.
	The influence of Plaferon LB on synthesis of interleukins. Int J Immunorehab 1996; 3: 96. (Abstract) (Exhibit 22)
23	Chikovani T et al.
	Plaferon LB as a blocker of neurotoxic effect of glutamate. Int. J Immunorehab 1997; 5: 46. (Abstract) (Exhibit 23)
24	Chikovani T et al.
	Immunopotential activity of Plaferon LB fractions. Int J Immunorehab 1998; (9): 5. (Abstract) (Exhibit 24)
25	Chikovani T et al.
	Different ways of therapy by Plaferon LB in patients with acute B viral hepatitis. Abstracts of International Falk Workshop, New Aspects in Hepatology and Gastroenterology; May 29-30, 1998; Tbilisi, Georgia. Abstract # 52. (Abstract) (Exhibit 25)
26	Chikovani T et al.
	Immunologic study of human placental factor. Eur J Allergy Clin Immun; 1999; 54 (52 S): 89. Abstract # P81. (Abstract) (Exhibit 26)

LATD	27	Chikovani T et al. Antioxidant action of immunomodulatory drug Plaferon LB in experimental thyroid pathology. Int J Immunorehab 1999; 12(S): 14-18. (Exhibit 27)
no translation not considered	28	Dolidze Z. et al. Plaferon antirecidence action on the children with idiopathic nephrotic syndrome. Bull Acad Sci Geo 1992; 145 (1): 209-11. (Exhibit 28)
LATD	29	Gagua M. et al. Investigation of polipeptide contents of Plaferon LB. Bulletin of Acad of Sci of Georgia 1996; 3(153): 450-452. (Exhibit 29)
	30	Gagua M. et al. Influence of Plaferon LB on the transcriptional activity of regenerating liver and kidney cells. International-European A.I.R.R. Conference; Tbilisi, 1999 October 4-9; Collection of reports: 11. (Abstract) (Exhibit 30)
	31	Gagua M. et al. Effect of Plaferon LB on morpho-functional activity of hepatocytes under conditions of hormonal disbalance in white rats. Bulletin of Georgian Acad of Sci 1999; 160 (3): 574-576. (Exhibit 31)
	32	Gurgenidze G. et al. Plaferon-induced in vitro inhibition of mitogen-activated T-lymphocyte proliferation in steroid-resistant asthmatic patients. Trans-Caucasian J Immunology 1999; 1 (2): 12-19. (Exhibit 32)
	33	Johnson DW et al. Cardioprotective effects of Plaferon-LB in canine model. First International Congress on Heart Disease-New Trends in Research, Diagnosis and Treatment; Washington DC, USA; 1999 May 16-19; Book of Abstracts: 46. Abstract # 30. (Abstract) (Exhibit 33)
	34	Macharadze D. et al. Plaferon-LB in immuno-rehabilitation of children with bronchial asthma. Int J Immunorehab 1998; 8: 67. Abstract # 249. (Abstract) (Exhibit 34)
	35	Maisuradze E. et al. Inhibition of Bee Venom Phospholipase A2 activity by Plaferon LB. Bulletin of the Georgian Academy of Sciences 1998; 157, (2): 317-319. (Exhibit 35)
	36	Beridze M. et al. Immunomodulator Plaferon Lb in the treatment of acute ischemic stroke. Int J Immunorehab 1999; 12: 161-165. (Exhibit 36)
↓	37	Metraveli D. et al. Influence of Plaferon-LB on clinical course of Hepatitis and Laboratory Data in Children. International Falk Workshop - New Aspects in Hepatology and Gastroenterology; May 29-30, 1998; Tbilisi, Georgia. Abstract # 195. (Abstract) (Exhibit 37)

KAM	<p>38 Metreveli D. et al. Long term results of treatment of B hepatitis with Plaferon LB. Int J Immunorehab 1999; 12: 43. Abstract # 169. (Abstract) (Exhibit 38)</p>
1	<p>39 Mikeladze D. et al. Influence of Plaferon upon main excitatory and inhibitory neurotransmitters of brain. Tbilisi 1995; 332-337. (Exhibit 39) * Translated Abstract only</p>
	<p>40 Nadareishvili Z. et al. Plaferon in the treatment of herpes zoster ganglioneuritis in intravenous drug users. Int Conf AIDS, Berlin 1993, June 6-11; 9 (1): 344. Abstract # PO-B08-1254. (Abstract) (Exhibit 40)</p>
	<p>41 Pantsulaia I. et al. Influence Plaferon-LB on changes in organs of immune system in case of experimental acute hyperthyroidism. Proceedings of the 4th Republic Scientific Practical Conference, Kutaisi, 1998 May 31; Collection of reports: 24. (Abstract) (Exhibit 41)</p>
	<p>42 Pantsulaia I. et al. Alteration of lymphocytes' proliferative activity in vitro under the influence of plaferon LB fractions. Proc Georgian Acad Sci, Biology Series 1999; 25 (1-6): 75-77. (Exhibit 42)</p>
	<p>43 Pantsulaia I. et al. Influence of PlaferonLB on proliferative activity of splenocytes in experimental hyper- and hypothyroidism. Int J Immunorehab 2000; 2 (2): 49. Abstract # 157. (Abstract) (Exhibit 43) * Translated Summary only</p>
	<p>44 Pantsulaia I. et al. Influence of Plaferon LB on the course of moderate periodontitis. Int J Immunorehabilitation 2000; 2 (2): 89. Abstract # 294. (Abstract) (Exhibit 44) * Translated Summary</p>
	<p>45 Pavliashvili D. et al. The effect of sublingual administration of Plaferon LB on metabolic disorders during viral hepatitis B. Georgian Med News 1999; 9 (54): 65-67. (Exhibit 45) * Summary only</p>
	<p>46 Rukhadze R. et al. Influence of plaferon LB on metabolic disorders in liver during experimental hyperthyroidism. Proc Georgian Acad Sci, Biol Ser 1998; 24 (1-6): 333-337. (Exhibit 46)</p>
	<p>47 Rukhadze R. et al. An interim report on the effect of Plaferon LB on metabolic changes in myocardium during experimental hyperthyroidism. Proc Georgian Acad Sci, Biol Ser 1998; 24 (1-6): 339-343. (Exhibit 47)</p>
V	<p>48 Rukhadze R. et al. Influence of Plaferon LB on some indices of liver mitochondria during experimental hyperthyroidism. Georgian Medical News 1999; 2: 7-9. (Exhibit 48) * Summary only</p>

Rukhadze R. et al.	49 Rukhadze R. et al. Influence of Plaferon LB on the metabolism of nitric oxide (NO) in case of Thyrotoxicosis. Bulletin of Georgian Academy of Science 1999; 160 (3): 580-582. (Exhibit 49)
Rukhadze R. et al.	50 Rukhadze R. et al. The influence of Plaferon-LB on some splenic morphometric indices during experimental hyper- and hypothyroidism. Int J Immunorehab 1999; 14: 117. Abstract # 76. (Abstract) (Exhibit 50)
Rukhadze R. et al.	51 Rukhadze R. et al. Influence of Plaferon LB on the metabolism of nitric oxide (NO) in case of hypothyroidism. Bulletin of Georgian Academy of Science; 2000, 161 (1): 156-158. (Exhibit 51)
Ryazantseva S. et al.	52 Ryazantseva S. et al. Immunomorphological changes in breast cancer as a result of preoperative administration of immunomodulator Plaferon. Herald of Oncology National Center, Russian Academy of Science; Clinical Investigations 1999; 4: 37. (Exhibit 52)
Shakarishvili R. et al.	53 Shakarishvili R. et al. The role of oxygen and nitrogen reactive species in pathogenesis of ischemic stroke. Report on Scientific Session of NATO, Tbilisi, Georgia, October 2001. In press. (Exhibit 53)
Tatishvili N. et al.	54 Tatishvili N. et al. Local use of Plaferon LB in rheumatology. Int J Immunorehab 1999; 12: 81. Abstract # 303. (Abstract) (Exhibit 54)
Telia A. et al.	55 Telia A. et al. Use of Plaferon LB in children with bronchial asthma. Int J Immunorehab 1997; 7: 139. (Abstract) (Exhibit 55)
Telia A. et al.	56 Telia A. et al. Preventive effect of Plaferon LB on hystamine-induced bronchoconstriction obstruction in guinea pig. Int J Immunorehab 1998; 9: 28. (Abstract) (Exhibit 56)
Telia A. et al.	57 Telia A. et al. Plaferon LB as an alternative preparation for treatment of bronchial asthma in children. Int J Immunorehab 1998; 10: 165-167. (Exhibit 57) * ABSTRACT ONLY
Telia A. et al.	58 Telia A. et al. Impact of Plaferon LB on bronchial and alveolar cell count and ventilatory function in patients with asthma. Int J Immunorehab 1999; 12 (S): 24. (Exhibit 58) * ABSTRACT TRANSLATION ONLY
Telia A. et al.	59 Telia A. et al. Influence of Plaferon LB on Proportion of Bal cells and Ventilatory Function in Patients with Asthma. Int J Immunorehab 1999; 12: 164-165. (Exhibit 59) * ABSTRACT ONLY
EXAMINER	DATE CONSIDERED 6/2/05

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